

December 20, 2016

URGENT DRUG RECALL

Dear Customer:

This official communication is to notify you that Zydus Pharmaceuticals USA Inc., is voluntarily recalling the mentioned below drug product at **RETAIL LEVEL**. As per the FDA's recommendation, Zydus is reclassifying this recall as Retail Level Recall, which was previously classified as distributor level recall on November 02, 2016.

| Product Name | Lot No. | Expiry | Pack Size | NDC No. | Distribution Start Date | Distribution End Date |
|------------------------------------|---------|---------|-----------|--------------|-------------------------|-----------------------|
| Bupropion HCL ER Tablet USP 300 mg | MS1667 | 01/2018 | 500's | 68382-354-05 | 05/23/2016 | 06/02/2016 |
| Bupropion HCL ER Tablet USP 300 mg | MS1667 | 01/2018 | 30's | 68382-354-06 | 06/01/2016 | 06/01/2016 |
| Bupropion HCL ER Tablet USP 300 mg | MS1668 | 01/2018 | 500's | 68382-354-05 | 05/31/2016 | 06/06/2016 |
| Bupropion HCL ER Tablet USP 300 mg | MS1669 | 01/2018 | 500's | 68382-354-05 | 06/06/2016 | 06/13/2016 |
| Bupropion HCL ER Tablet USP 300 mg | M601708 | 03/2018 | 30's | 68382-354-06 | 08/23/2016 | 09/09/2016 |
| Bupropion HCL ER Tablet USP 300 mg | M601515 | 03/2018 | 500's | 68382-354-05 | 06/13/2016 | 06/15/2016 |
| Bupropion HCL ER Tablet USP 300 mg | M601516 | 03/2018 | 500's | 68382-354-05 | 06/15/2016 | 06/27/2016 |
| Bupropion HCL ER Tablet USP 300 mg | M602920 | 04/2018 | 500's | 68382-354-05 | 06/27/2016 | 06/30/2016 |
| Bupropion HCL ER Tablet USP 300 mg | M602921 | 04/2018 | 500's | 68382-354-05 | 06/30/2016 | 07/18/2016 |
| Bupropion HCL ER Tablet USP 300 mg | M605399 | 04/2018 | 500's | 68382-354-05 | 08/01/2016 | 08/18/2016 |
| Bupropion HCL ER Tablet USP 300 mg | M602937 | 04/2018 | 500's | 68382-354-05 | 07/18/2016 | 07/20/2016 |

| Product Name | Lot No. | Expiry | Pack Size | NDC No. | Distribution Start Date | Distribution End Date |
|------------------------------------|---------|---------|-----------|--------------|-------------------------|-----------------------|
| Bupropion HCL ER Tablet USP 300 mg | M602938 | 04/2018 | 500's | 68382-354-05 | 07/26/2016 | 07/27/2016 |
| Bupropion HCL ER Tablet USP 300 mg | M602939 | 04/2018 | 500's | 68382-354-05 | 07/26/2016 | 08/01/2016 |
| Bupropion HCL ER Tablet USP 300 mg | M603988 | 06/2018 | 500's | 68382-354-05 | 08/22/2016 | 09/06/2016 |

Zydus Pharmaceuticals USA Inc. has decided to initiate voluntary recall of the above drug product lots based on the impact assessment from an investigation of an Out Of -Specification results observed for lot No: MS1667 which did not meet dissolution specification of stability sample analysis at 6 months 25°C / 60%. Based on the Investigation, the root cause of the reported OOS is identified to be usage of 61 station compression machine. As an impact assessment, above listed batches compressed on the 61-station compression machine shall be recalled from the market.

Zydus Pharmaceuticals USA Inc. advises its customers that have this product in stock to discontinue use/dispense/distribute and return it to Inmar Pharmaceuticals Services as per the details furnished below. If you have further distributed this product, please identify your customers, and provide them with this recall notice as this recall is being conducted at RETAIL LEVEL.

Your assistance is appreciated and necessary to prevent further product usage.

Through this communication, at our cost, we request that you please return all of the above referenced drug product and associated lots in your current inventory. To facilitate this recall, please do the following actions:

1. Examine your available stock for the presence of above referenced lots of the drug product listed within this recall.
2. If you have the any of the listed lot numbers of the drug product in your stock, please discontinue any further distribution and quarantine it immediately. The quarantined product should be returned to: Inmar Pharmaceutical Service, South Dock, 4332 Empire Rd, Fort Worth, TX 76155. Zydus will issue a credit memo based on the corresponding units within your return to Inmar.
3. Please complete the enclosed "PRODUCT RECALL RESPONSE FORM" and fax it to us at 1-817-868-5362 or email it to rxrecalls@inmar.com. Even if you do not possess any inventory of the lots being recalled, we would appreciate your cooperation and help by still filling in and returning the form to us.
4. In the case that the identified product was distributed to a retail customer for further dispensing, please identify your customers and notify them at once of this product recall. Please include a copy of this letter with your notification to insure proper handling and return of the product.

Please complete and return the enclosed response form as soon as possible.

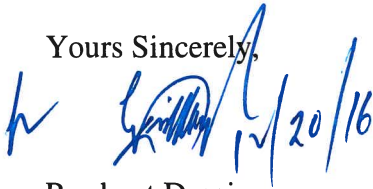
If you have any questions about product safety issue, then please call Zydus Pharmaceuticals Drug Safety/ Medical Affairs at 1-877-993-8779 Option# 2.

If you have any questions in regards to return logistics or any and other issue, then please call Recall Services at 1-800-967-5952.

This recall is being made with the knowledge of the Food and Drug Administration.

We apologize for any inconvenience this voluntary recall may have caused you.

Yours Sincerely,



Prashant Desai

Sr. Vice President – Technical Operations

Zydus Pharmaceuticals USA Inc

PRODUCT RECALL RESPONSE FORM**URGENT DRUG RECALL-RETAIL LEVEL**

Please complete the required information and fax to **1-817-868-5362**

or email to rxrecalls@inmar.com

To the Attention of Drug Safety/ Recall Services-Zydus Pharmaceuticals USA Inc.

| Product Name | Lot No. | Expiry | Pack Size | No. of Bottle to be Returned |
|------------------------------------|---------|---------|-----------|------------------------------|
| Bupropion HCL ER Tablet USP 300 mg | MS1667 | 01/2018 | 500's | |
| Bupropion HCL ER Tablet USP 300 mg | MS1667 | 01/2018 | 30's | |
| Bupropion HCL ER Tablet USP 300 mg | MS1668 | 01/2018 | 500's | |
| Bupropion HCL ER Tablet USP 300 mg | MS1669 | 01/2018 | 500's | |
| Bupropion HCL ER Tablet USP 300 mg | M601708 | 03/2018 | 30's | |
| Bupropion HCL ER Tablet USP 300 mg | M601515 | 03/2018 | 500's | |
| Bupropion HCL ER Tablet USP 300 mg | M601516 | 03/2018 | 500's | |
| Bupropion HCL ER Tablet USP 300 mg | M602920 | 04/2018 | 500's | |
| Bupropion HCL ER Tablet USP 300 mg | M602921 | 04/2018 | 500's | |
| Bupropion HCL ER Tablet USP 300 mg | M605399 | 04/2018 | 500's | |
| Bupropion HCL ER Tablet USP 300 mg | M602937 | 04/2018 | 500's | |
| Bupropion HCL ER Tablet USP 300 mg | M602938 | 04/2018 | 500's | |
| Bupropion HCL ER Tablet USP 300 mg | M602939 | 04/2018 | 500's | |
| Bupropion HCL ER Tablet USP 300 mg | M603988 | 06/2018 | 500's | |

No. of Bottles Purchased : _____

No. of bottles Consumed : _____

No. of bottles in Possession : _____

No. of bottles to be returned : _____

No. of Returns kit required : _____



Please mark as applicable

☐ We currently do not have any inventory of the above listed Lot/bottles

☐ We are notifying our customers

☐ We have identified and notified my customers that were shipped or may have been shipped this product by _____;

☐ Attached is the list of customers who received/ may have received this product. Please notify my customers.

Any adverse event associated with recalled product? ☐ Yes ☐ No

If yes, please explain:

Please check appropriate box to describe your business

☐ Wholesaler/Distributor

☐ Retailers

☐ Grocery Corporate Headquarters

☐ Repackager

☐ Manufacturer

☐ Pharmacy- Retail

☐ Hospital/ Medical Facility

☐ Hospital Pharmacies

☐ Medical Laboratory

☐ Other: _____

Name: _____

Title: _____

Tel Number: _____

Firm Name: _____

DEA# _____

Address: _____

City/ State: _____

Zydus Pharmaceuticals (USA) Inc.

73 Route 31 North • Pennington, NJ 08534

Phone: 609-730-1900

Fax: 609-730-1998



If you have not purchased, the concerned lot directly from Zydus Pharmaceuticals USA Inc., then please provide details of your wholesaler: _____ (Name, City)

Signature: _____

Date: _____